



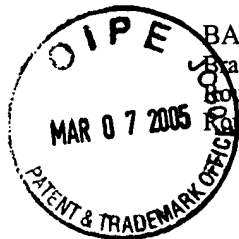
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/389,504	09/03/1999	TOM WESTBERG	F-5489	5480

7590

12/26/2001

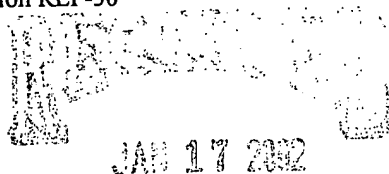


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JAN 17 2002

EXAMINER

BIANCO, PATRICIA

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 12/26/2001

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RYAN KROGHOLZ & MANION S.C.

Please find below and/or attached an Office communication concerning this application or proceeding.

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FENWAL/PATENT LAW

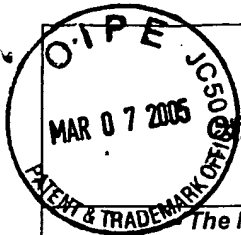
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TECHNOLOGY CENTER P3700

DOCKETED

DUE: 3/26/2002

CLERK: [Signature]

CASE	F6-5489 US
DRY. DATE	3-26-02
FINAL DATE	6-26-02
SUBJ. CI	Office Action / 3 Mes



Office Action Summary

Application No. 09/389,504	Applicant(s) WESTBERG ET AL.	
Examiner Patricia M Bianco	Art Unit 3762	

The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 September 1999.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 9-20, 25-27, 29-34, 40 and 41 is/are rejected.
- 7) ☒ Claim(s) 5-8, 21-24, 28, 35-39 and 42-46 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

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Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

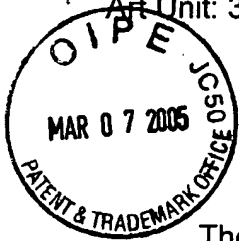
Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

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DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 4, 9-20, 25-29, & 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Giesler et al. (5,746,708). Giesler et al. (hereafter Giesler) discloses a blood processing system having a blood draw (donor flow) tube, a separation element for separating the whole blood into components, a pump station wherein the pump is in communication with the tubes, and a controller that controls the operation of the pump such that it operates in multiple modes. Further, the system includes a cassette body that incorporates the tubing of the pump and blood components tubing. The pump has multiple pumping stations and valves for directing fluid flow throughout the cassette.

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The pump directs whole blood from the donor access to the separation element for separating wherein the components are red blood cells and plasma. After separation of the whole blood into components, the pump directs the separated components into their respective storage containers.

Claims 1, 4, 9-15, 17-20, 23, 25-27, & 29-32 are rejected under 35 U.S.C. 102(e) as being anticipated by Brierton et al. (5,795,317). Brierton et al. (hereafter Brierton) discloses a blood processing apheresis system for and method of separating whole blood into its components. Brierton has a separating (processing) device for separating whole blood into its components (plasma, red blood cells, and platelets). Plasma and red blood cell collection and return lines are included for returning, if desired, at least some of the plasma and/or red blood cells to the patient. The system also includes plasma and red blood cell collection lines for delivering the components to their respective storage containers. The system further includes a pump assembly that includes valves for moving blood and the separated components throughout the system. The tubing segments are in communication with the pump assembly. The tubing segments are also provided on a cassette body for use in the system. The pump operates in multiple stages. In the processing mode whole blood is sent to the processing device and separated into its components. After separation, the pump assembly directs separated cells and plasma to their containers. Brierton also discloses the use of a controller, such as a microprocessor, to control the entire procedure.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2, 3, 30, 31, 40, & 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giesler et al. ('708) in view of Bormann et al. (5,738,796). Giesler et al. substantially discloses the invention as claimed except for including a leukocyte filter in the component collection channel.

Bormann et al. (hereafter Bormann) discloses a system and method for separating whole blood into its components and further separating leukocytes from the separated components in procedures such as apheresis. After separation, the separated component is passed through a leukocyte depleting filter before it is stored in its storage container. It is desirable to remove as many leukocytes from separated

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plasma or red blood cells since leukocytes can cause undesirable effects when administered to another patient.

It would have been obvious to one having ordinary skill in the art, at the time of the invention, to have modified the system of Giesler to include a leukocyte filter in one of the component transfer lines since it is desirable to remove as many leukocytes from separated plasma or red blood cells to prevent any undesirable effects when administering the separated plasma or cells to another patient.

Claims 2, 3, 30, 31, 40, & 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brierton et al. ('317) in view of Bormann et al. (5,738,796). Brierton et al. substantially discloses the invention as claimed except for including a leukocyte filter in the component collection channel.

Bormann et al. (hereafter Bormann) discloses a system and method for separating whole blood into its components and further separating leukocytes from the separated components in procedures such as apheresis. After separation, the separated component is passed through a leukocyte depleting filter before it is stored in its storage container. It is desirable to remove as many leukocytes from separated plasma or red blood cells since leukocytes can cause undesirable effects when administered to another patient.

It would have been obvious to one having ordinary skill in the art, at the time of the invention, to have modified the system of Brierton to include a leukocyte filter in one of the component transfer lines since it is desirable to remove as many leukocytes from

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separated plasma or red blood cells to prevent any undesirable effects when administering the separated plasma or cells to another patient.

Allowable Subject Matter

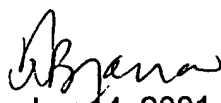
Claims 5-8, 21-24, 28, 35-39, & 42-46 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

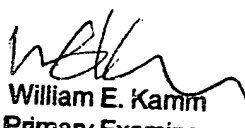
Conclusion

Any inquiry concerning the rejections contained within this communication or earlier communications should be directed to examiner Tricia Bianco whose telephone number is (703) 305-1482. The examiner can normally be reached on Monday through Fridays, alternating Fridays off, from 9:00 AM until 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The official fax numbers for the organization where this application or proceeding is assigned is (703) 872-9302 for regular communications and for After Final communications (703) 872-9303.

Tricia Bianco
Patent Examiner
Art Unit 3762

tmb 
December 14, 2001


William E. Kamm
Primary Examiner
